The Michigan Department of Community Health
Institutional Review Board for Human Subject Research

Baker Olin West Room 216, 3423 N. MLK Jr. Blvd., Lansing, MI 48909

(Phone: (517) 335-9080, fax: (517) 335-9195)

MDCH IRB REVIEW APPLICATION

Completion of Sections 1-4 is mandatory for all applications. Note: To complete this application, type answers directly into shaded answer areas.

SECTION 1 - PROJECT IDENTIFICATION (completion of this section is mandatory)

1.1 "Responsible MDCH Employee" (employee responsible for the MDCH role in this research):

1.2 "Responsible MDCH Employee's" Signature: (required to assure departmental responsibility for the protection of human subjects and adherence to MDCH IRB requirements):

_____

1.3 "Responsible MDCH Employee's" Agency/BOC/Division:

1.4 Title of Research Project (title must be the same on all study documents):

1.5 Source of Funding (include the both the name and type of the agency, e.g. CDC-federal):

1.6 Grant Number (**REQUIRED** for all federally funded projects):

1.7 Project Type (Check all that apply)

☐ Direct human subject participation involving invasive treatments, procedures, or experimentation

☐ Direct human subject participation using surveys, interviews, focus groups, observations, etc.

☐ Indirect human subject participation using human data or biological specimens that were collected or will be collected for non-research purposes, or material that will be discarded

1.8 Check which FDA-regulated test articles (i.e., investigational drugs, biologics or devices) will be used in this project? (Check all that apply)

☐ No test article used

☐ Drug or biologic used IND#: Trial phase:

☐ Device used IND#: Risk level (significant or insignificant):

1.9 What is the projected date to begin this research?

1.10 What is the projected date to complete this research?

1.11 List any other IRBs that will review this project:

1.12 Describe any potential conflicts of interest between the researchers and the study sponsors:

1.13 Name of Principal Investigator (if not MDCH employee):

********** **END of Section 1** **********

SECTION 2 - APPLICATION TYPE (completion of this section is mandatory)

2.1 Does the research involve direct human subject participation? ☐ YES ☐ NO

If **YES**, complete Sections 1-10 **AND** check other sections below that apply to the research. If **NO**, skip to 2.2.

- ☐ Surveys, interviews, focus groups, observations, etc. – **complete also Section 11**
- ☐ Blood removal – **complete also Section 12**
- ☐ Tissue removal; investigational drugs, biologics or devices; approved drugs, biologics or devices; ionizing radiation; organ/tissue/cell transfer; gene transfer – **complete also Section 13**
- ☐ Genetic analysis – **complete also Section 14**
- ☐ Research on existing human-derived data or biological specimens, previously collected or to be collected in the future for non-research purposes, or to be discarded – **complete also Section 15**

2.2 Does the research involve only indirect human subject participation? ☐ YES ☐ NO

If **YES**, complete Sections 1-4 and Section 15.

********** **END of Section 2**********

SECTION 3 - RESEARCH INFORMATION (completion of this section is mandatory)

3.1 Provide a concise (300 words) summary of the research, including the following information:

FOR RESEARCH THAT INVOLVES DIRECT HUMAN SUBJECT PARTICIPATION

- age, gender, ethnicity and race distribution of the study population, including vulnerable populations
- what will be done to the participants for research purposes
- whether or not the research records will be linkable in any way to the research participants
- informed consent process to be employed

FOR RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

- information on the kind and source of data or biological specimens
- what will be done with data or biological specimens
- how data will be linkable to the persons from whom the data or biological specimens are derived
- informed consent process to be employed

(Type summary here)

3.2 What documents are you submitting with this application? Check only those that are applicable.

- ☐ Study protocol
- ☐ Informed consent instrument(s)
- ☐ Investigator's brochure, solicitation materials for subject recruitment (specify):
- ☐ Survey instruments
- ☐ HIPAA-Compliant Request Form for waiver of authorization
- ☐ IRB review/approval documents from institution of principle investigator, if not MDCH
- ☐ Other (specify)

**********END of Section 3 **********

SECTION 4 - INFORMED CONSENT PROCESS (completion of this section is mandatory)

4.1 Check the type(s) of informed consent process that will be used? Check all that apply.

- ☐ A comprehensive written document, signed by the participant (or legal representative)
- ☐ A comprehensive written document, that is not signed*
- ☐ A short written document stating that all required elements have been presented orally to the participant (or legal representative) and signed by either of them*
- ☐ The assent of children that documents their willingness to participate in research (required from children who are capable of comprehending the nature of the study)
- ☐ Request to alter or waive informed consent requirement in whole or in part. * ** Specify:

  * In certain cases the IRB may approve research that alters, some or all of the required elements of informed consent, waives the requirement for signed consent, or waives the requirement for consent entirely. The provisions of 46.116 or 117 that permit these exceptions must be explained when such exceptions are requested.

  Submit HIIPAA-Compliant Request Form for waiver of authorization, **if applicable.

4.2 Submit texts of all project-specific informed consent instruments for approval by the MDCH IRB and indicate what consent documents are appended.

4.3 Check below who may act on the behalf of the subject to give consent to participate in this research. Check all that apply.

- ☐ the adult participant in the research himself/herself
- ☐ the legal guardian of the participant in the research
- ☐ the next-of-kin of an adult participant (specify relationship) ccc
- ☐ one parent of a child who participates in the research
- ☐ **only** both parents of a child who participates in the research
- ☐ the assent of a child who participates in the research

4.4 Specify the criteria to be used to determine whether or not assent to participate should be obtained if children are among the research participants.

Consult 45 CFR 46.116 and 46.117 – for guidance on the elements of informed consent.

The informed consent process requirements are found in 45 CFR 46.116 and the documentation of informed consent requirements in 45 CFR 46.117. Information must be presented in a manner that will enable someone to voluntarily decide whether or not to participate in the research.

Informed consent is a process to protect the rights of human research participants and it should not be considered primarily a form to protect the researcher.

********** **END of Section 4**********

Sections (5-14) Are For Research That Involves Direct Human Subject Participation

SECTION 5 - CHARACTERISTICS OF HUMAN PARTICIPANTS (Leave this section blank **only if** there is no direct human participation in the research)

5.1 What health/disease categories (e.g. healthy participants, diabetics, etc.) **are involved?**

5.2 How many participants in each health/disease category will be recruited?

5.3 What will be the total duration of involvement of a participant in the study?

5.4 Describe if the research involves a health problem that may be relevant to certain populations.

5.5 Provide justification for research limited to a particular age, gender, ethnic or racial group?

5.6 Check which of the following vulnerable populations may be research participants?

- ☐ none
- ☐ children (age <18 years)
- ☐ mentally compromised or decisionally impaired persons (specify)
- ☐ women with child-bearing (reproductive) potential
- ☐ pregnant or lactating women
- ☐ fetuses *(ex utero)*
- ☐ *in vitro* fertilization
- ☐ prisoners

5.7 Check which of the following populations that could be subject to coercion may be among the participants?

- ☐ none
- ☐ economically (coercion may result from payments to participants) or educationally deprived
- ☐ patients of the investigator
- ☐ students of the investigator
- ☐ employees of the investigator

5.8 Justify the inclusion of research participants considered vulnerable or susceptible to coercion.

5.9 What are the criteria for inclusion, and exclusion, of research participants?

********** **END of Section 5**********

SECTION 6 - PARTICIPANT RECRUITMENT PROCEDURES (Leave this section blank **only if** there is no direct human participation in the research)

6.1 How (e.g. existing list, random) will potential research participants be identified for recruitment?

6.2 Where (e.g. at home, in a clinic) will the potential research participants be recruited?

6.3 How (e.g. phone call, brochure, letter) will the potential research participants be recruited?

6.4 If recruitment materials (e.g. advertisements, letters) are to be used are they attached? ☐ YES ☐ NO

6.5 If the research involves a health problem that may have specific relevance to certain ethnic, racial or other minority groups, what special measures will be taken to optimize recruitment of participants from these groups?

********** **END of Section 6**********

SECTION 7 - EXPERIMENTAL TREATMENTS and PROCEDURES (Leave this section blank **only if** there is no direct human participation in the research)

7.1 Research that involves experimental procedures requires MDCH IRB approval of the study protocol.

The protocol document shall bear a date, and a title matching the title shown in this application. It should describe goals of the study, background information, specific aims, experimental design, statistical analysis of results, subjects of the research, risks and benefits of treatments or procedures, and significance of the outcomes. Indicate here if protocol is attached.

Is the study protocol attached? ☐ YES ☐ NO

7.2 Describe any participant compensation.

7.3 Describe treatments/procedures (non-survey) participants will undergo for this research.

7.4 Will the participants complete any interviews or survey instruments, or attend group meetings for the purposes of this research?

☐ **YES** ☐ **NO** If **YES,** you must also complete Section 11.

7.5 Will blood be taken from the participants for the purposes of this research?

☐ **YES** ☐ **NO**

If **YES,** you must also complete Section 12.

7.6 Please state whether any of the following will apply for the purposes of this research:

Biological specimens (other than blood) will be taken from the participants, investigational, FDA-exempted drugs, biologics or devices or FDA-approved drugs, biologics or devices will be administered or applied to the participants, organs, tissues or cells from other humans will be administered or applied to the participants, participants will be exposed to ionizing radiation, or genetic material will be transferred to participants in the course of the research?

☐ **YES** ☐ **NO** If **YES**, specify which of these apply**:**

If **yes** to any of the questions above, provide information by completing the applicable parts of Section 13.

7.7 Will genetic analysis be performed on any biological specimen to be acquired in conjunction with this research?

☐ **YES** ☐ **NO** If **YES**, you must also complete Section 14.

********** **END of Section 7** **********

SECTION 8 - RISKS AND BENEFITS OF THE RESEARCH (Leave this section blank **only if** there is no direct human participation in the research)

8.1 To indicate your judgment of the overall research-related risk of harm to participants choose ONE of the three levels below*

☐ Minimal risk

☐ Moderate risk

☐ High risk

* A minimal risk is considered one where the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

8.2 What direct risks could participants face by participating in this research, and what measures will be taken to minimize each risk?

8.3 If "vulnerable populations" or populations susceptible to coercion are among the research participants, what additional measures will be taken to minimize risks that may affect them?

8.4 What indirect risks (if any) to the public or community could result from this research?

8.5 What potential direct benefits (if any) could this research provide participants?

8.6 What potential indirect benefits could this research provide the public or others?

********** **END of Section 8** **********

SECTION 9 - RESEARCH RECORDS (Leave this section blank **only if** there is no direct human participation in the research)

9.1 Will research records be linkable to the participants by any identifiers, including names, registration numbers, code numbers, etc entered into the records? ☐ **YES** ☐ **NO** (If **NO**, skip to 9.3)

9.2 If information in the research records was revealed, could it place the participants (or others) at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputation?

☐ YES ☐ NO

9.3 Describe the procedures that will be taken to ensure the privacy of the participants and to preserve the confidentiality of private information, including any plans to seek a "Certificate of Confidentiality" or "Director's Medical Research Project" designation. (Privacy is the right of an individual to control his or her personal information whereas confidentiality is the obligation of the researcher to protect private information they receive.)

********** **END of Section 9** **********

SECTION 10 - COSTS OF THE RESEARCH (Leave this section blank **only if** there is no direct human participation in the research)

10.1 Describe any and all costs that the participant could incur by their participation, including indirect costs such as to insurance.

********** **END of Section 10** **********

SECTION 11 - INTERVIEWS, SURVEYS OR GROUP MEETINGS INVOLVING THE RESEARCH PARTICIPANTS

(complete this section if your answer to Question 7.4 was "Yes")

11.1 Describe the methods that will be used to collect information relevant to this section.

11.2 What is the anticipated duration and number of the sessions to collect this information?

11.3 Describe the information that will be collected by interview, survey, or group meetings.

11.4 If information will be collected by telephone, explain the consent procedure.

11.5 How will the privacy of the participants be protected while collecting information?

11.6 Could revelation of collected information place the participant, or others, at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputation?

☐ **YES** ☐ **NO** If **YES**, explain.

11.7 How will the information be recorded? Check all applicable entries.

- ☐ Text entered by investigators
- ☐ Text entered by the subject
- ☐ Voice of the subject
- ☐ Image of the subject
- ☐ Other (specify):

11.8 Describe how any survey records (instruments, recordings, etc) will be labeled or identified to provide a direct, or indirect link, to the participant.

11.9 Are survey instruments and letters of prior announcement of intent to contact attached? ☐ YES ☐ NO

********** **END of Section 11** **********

SECTION 12 - BLOOD TO BE TAKEN FROM PARTICIPANTS FOR THE PURPOSES OF RESEARCH

(Complete this section if your answer to Question 7.5 was "**YES**," otherwise leave blank.)

If genetic information is to be obtained from the blood, you must also complete section 14.

12.1 By what route and method will blood be taken for the purposes of this research?

12.2 State the number of times, the intervals and the time-span over which blood will be taken?

12.3 What is the largest volume of blood to be taken from a participant during a single draw?

12.4 What is the total volume of blood to be taken from a participant during the entire project?

12.5 Describe the participant's rights to financial benefit from research using his or her blood.

12.6 Describe the process for disposal of blood specimens, including all rights of the participant and obligations of the researcher, if there are plans to store the material for future use.

**********END of Section 12**********

SECTION 13 - TISSUE TO BE TAKEN; INVESTIGATIONAL, FDA-EXEMPTED DRUGS, BIOLOGICS OR DEVICES; FDA-APPROVED, NON-INVESTIGATIONAL DRUGS, BIOLOGICS OR DEVICES; EXPOSURE TO IONIZING RADIATION; ORGANS, TISSUE OR CELLS TO BE ADMINISTERED; GENETIC MATERIAL TO BE TRANSFERRED

Complete this section **only if** your research involves any of the above categories.

13.1 Provide any additional information appropriate for the special considerations of "Research that is Infrequently Sponsored by the MDCH." The special considerations for these types of research are discussed in Section #13 of the instructions/information document, under "RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN PARTICIPANTS."

END of Section 13

SECTION 14 - GENETIC ANALYSIS OF BIOLOGICAL SPECIMENS TO BE OBTAINED FROM RESEARCH PARTICIPANTS

(Complete this section if your answer to Question 7.7 was "**YES**.")

14.1 Describe the biological specimens that will be genetically analyzed.

14.2 What particular genetic information will be acquired?

14.3 What is the specific purpose of the genetic analysis?

14.4 Describe any potential risk the genetic information could pose to insurability, employability or social esteem of the subject, or others.

14.5 Describe how any genetic information and material will be kept confidential and secure. (Confidentiality refers to protection from unauthorized disclosure whereas security applies to the spectrum of physical, technical and administrative safeguards to protect the integrity, availability and confidentiality of both the genetic information and the biological material).

14.6 Describe the process for providing genetic information to the participant (include the option to know or not to know the results, circumstances involving genetic abnormalities or parenthood, and circumstances that constitute a moral obligation to inform the participant).

14.7 Describe the circumstances involving any provision for genetic counseling.

14.8 Describe the participant's rights to any potential financial benefit that may result from research using his or her genetic material.

14.9 Describe the process for disposal of the biological material, including all rights of the participant and obligations of the researcher, if there are plans to store the material for future use.

END of Section 14

END OF SECTIONS FOR RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN PARTICIPANTS

SECTION 15 - RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

Complete this section for research that uses: a) existing human data or biological specimens that were collected previously for a purpose other than this research, or b) human data or biological material that will be collected in the future for non-research purposes. The biological material must be residual material or material that would otherwise be discarded.

(Please note that if the research involves both direct human subject participation and also a component that does not involve direct human subject participation, you must complete both the appropriate sections of 5-14 and section 15.)

15.1 **State why & how the existing data or biological materials were collected, or how data or biological materials to be used in this research will be collected for non-research purposes.**

15.2 **Were the existing data or specimens originally stored in a way that could reveal the identity of the person from whom the material originated? ☐ YES ☐ NO** (If **NO** skip to the checklist on page 10)

15.3 **Will the research records carry any identifiers that could link the information to the person, from whom the material originated? ☐ YES ☐ NO** (If **NO** skip to the checklist on page 10)

15.4 **What type of data and/or biological specimens will be used for research?**

15.5 **From how many persons did/will the data or biological specimens originate?**

15.6 **From what source(s) will the data or biological specimens be procured?**

15.7 **How will the investigators gain access to the data or biological specimens?**

15.8 **If the data or biological specimens were originally collected for non-research purposes, have the persons from whom the material originated agreed that the material might also be used for research purposes? ☐ YES ☐ NO**

15.9 **Does use of the data or biological specimens involve information, which if revealed, could place someone at risk of criminal or civil liability, or be damaging to their financial standing, employability or reputation? ☐ YES ☐ NO**

15.10 **How will the permission of the persons, from whom the data or biological specimens originated, be obtained to use the material for research purposes?**

15.11 **What measures will be taken to keep the research records confidential?**

15.12 **Describe any access that researchers will have to information that is not essential to the research, what will be done with this non-essential information, and how it will be protected.**

15.13 **Could the research to be conducted on the data or biological specimens reveal information of potential benefit to the persons from whom the material originated? ☐ YES ☐ NO** If **YES**, describe plans to inform participants about their rights**:**

15.14 **Could the research lead to the development of a commercial product that may bring financial benefit to the investigators and/or the sponsor? ☐ YES ☐ NO** If **YES**, describe plans to inform participants about their rights**:**

END of Section 15

MDCH IRB REVIEW REQUEST COMPLETENESS CHECKLIST

Completion of this section is mandatory. Numbers in parentheses refer to the sections of the application, where the corresponding issues appear.

For each item shown in the following list the applicant should check off the cell to the left of each applicable item to indicate that it has been carried out and/or submitted. The column to the right is for MDCH IRB use only.

Investigator Completes		MDCH IRB
☐	Documents are dated to indicate the latest revisions.	
☐	The same project title is on the application, the study protocol & the informed consent documents	
☐	Name of the "Responsible MDCH Employee" is shown.	
☐	"Responsible MDCH Employee's" signature appears on printed copies (1.2).	
☐	Printed copies of all project-specific consent instruments submitted (3.2, 4.2)*.	
☐	Date of most recent version of consent document is shown.	
☐	Printed copies of survey instruments submitted (3.2, 11.9)*.	
☐	Printed copy of Study Protocol submitted (3.2, 7.1)*.	
☐	Printed copies of solicitation materials for subject recruitment submitted (3.2, 6.4)*.	
* Indicates these documents are required when these sections of the application form apply		

FOR MDCH IRB OFFICE USE ONLY:

Date Submitted:	
Decision final:	
Notice sent:	

Processed by:	
Review time:	

The Michigan Department of Community Health (MDCH)
Institutional Review Board (IRB) for Human Subject Research

Information and Instructions Regarding Research Approval

This document contains only information and instructions. The "MDCH IRB Review Application" is a separate document. Submit **only** the actual application to request IRB review.
Submit **two signed copies** of the completed application to: the MDCH IRB, Room 216 Baker Olin West, 3423 N. MLK Jr. Blvd., Lansing, MI 48909 (phone 517-335-9080; fax 517-335-9195).

REQUIREMENTS FOR REVIEW AND APPROVAL OF HUMAN RESEARCH ACTIVITIES

Institutional Review Boards (IRBs) review, approve and monitor research that directly or indirectly involves living persons, their tissues or personal information, in order to protect the rights of the participants. There are two main considerations to determine if a particular activity needs IRB review by the MDCH IRB:

Does the activity involve the systematic collection/analysis of data, from or about living individuals, with the intent to generate new knowledge?

This can involve an intervention or interaction with living individuals, or only involve the collection of, release of, or access to identifiable private information or biological specimens from or about living individuals. Since the definition of research (for IRB purposes) may be difficult, only the IRB can determine whether activities that involve obtaining and analyzing data to generate new knowledge constitute research in this context.

MDCH IRB review is required for:
All research involving living human participants, **if one or more** of the following apply:

1) the research is sponsored by the department, **or**
2) the research is conducted by or under the direction of any employee or agent of the department in connection with his or her institutional responsibilities, **or**
3) the research is conducted by or under the direction of any employee or agent of the department using any facility of the department, **or**
4) the research involves the use of the department's **non-public** information to identify, **or** contact, human research participants or prospective participants.

Research may not begin without written MDCH IRB approval. Any changes to an approved study must have written MDCH IRB approval before they are implemented (except when necessary to eliminate an apparent immediate hazard to the subject). Any unexpected problems or changes in the research that could potentially be a human subjects concern must be reported immediately to the MDCH IRB chair.

The legal basis for MDCH IRB authority is Title 45 Code of Federal Regulations Part 46. This document and other IRB material can be found at: http://ohrp.osophs.dhhs.gov/

HOW TO SUBMIT MATERIAL FOR IRB REVIEW

Submit two printed copies of the application form and any other relevant documents to the Michigan Department of Community Health, Institutional Review Board, Room 216 Baker Olin West, 3423 N. MLK Jr. Blvd., Lansing, MI 48909, (phone 517-335-9080; fax 517-335-9195). **The "Responsible MDCH Employee" must sign the application form.**

The MDCH IRB will review the proposed activity and send notification to the "Responsible MDCH Employee" with a copy to the responsible Departmental Bureau, Center or Office director. The "Responsible MDCH Employee" must be a MDCH employee and should be the person most directly responsible for the Department's involvement in the activity. **Written communication between the MDCH IRB and all others involved in the research will be through the "Responsible MDCH Employee," including communication with researchers outside of the department.**

Written IRB approval will include the approval date and expiration date of the approval. All approvals expire one year from the approval date unless otherwise indicated on this form. Whenever a consent document, study protocol or other study material is revised and receives IRB approval, or whenever a project receives continuation approval (renewal), the newly assigned approval date **shall** appear on all subsequent copies of the study documents.

The "MDCH IRB Review Application" is designed both for research that involves the direct participation of living persons in the research and also research done only on a living individual's personal information or biological material. **All sections of the application that are not relevant should be left blank.**

The application has four main parts:

General Information on the Project (Sections 1–4): must be completed.

Research That Involves Direct Human Subject Participation (Sections 5–14): complete Sections 5-10 and any relevant sections of 11-14, if living persons participate directly in any way or in any part of the research.

Research That Does Not Involve Direct Human Subject Participation (Section 15): complete if living persons do not participate directly in the research but their personal information or biological material is used for the research.

Please note that if the research involves both direct human subject participation and also a component that does not involve direct human subject participation, complete both the appropriate sections of 5-14 and section 15.

Completeness Check List: this is to help both the researcher and the MDCH IRB assure that the application documents have been prepared appropriately and are complete.

ABOUT THE APPLICATION

SECTIONS 1-4, REQUIRED INFORMATION FOR ALL APPLICATIONS

Section 1: Project Identification: information the MDCH IRB needs for tracking and other purposes

Section 2: Application Type: directs the applicant to the relevant sections of the application

Section 3: Information on the Research: concise (limit 300 words) description of research

Section 4: Information on the Informed Consent Process: including requests for waivers

Copies of the most current informed consent instrument(s) must be submitted with the application.

In certain cases the IRB may approve research that does not include, or that alters, some or all of the required elements of informed consent, waives the requirement for signed informed consent, or waives the requirement for informed consent. **The provisions of 46.116 or 117 that permit these exceptions must be explained when such exceptions are requested.**

A "HIPAA-Compliant Request Form" may also need to be submitted when requesting a waiver of authorization. For further information, consult the HIPAA Informed Consent Guidelines posted on the **MDCH HIPAA Internet Web site. (http://www.michigan.gov/mdch/0,1607,7-132-2945_24020---,00.html)**

SECTIONS 5-14: RESEARCH THAT INVOLVES DIRECT HUMAN SUBJECT PARTICIPATION

Section 5: Characteristics of Human Research Participants

The IRB needs comprehensive information about study participants, in order to determine whether they: are suitable for the type of research, are recruited in reasonable numbers, will participate in the study long enough to obtain valid new knowledge, will be vulnerable or prone to coercion and will be selected equitably. Equitable selection requires that age, gender, ethnic and racial groups within the study communities are fairly represented among the participants in the study, unless the study focuses on a specific subset of the community, for justifiable reasons.

Section 6: Participant Recruitment Procedures

All interested members of the community should have the opportunity to participate but they should not be coerced. Minority groups should be actively encouraged to take part in the research, especially if the health problem under study affects that group with a high prevalence or presents itself in some unique way to them.

Section 7: Experimental Treatments or Procedures Involving Human Participants

A study protocol contains the elements of a scientific plan in sufficient detail to explain the experimental design, the project's merits, and the significance of the new knowledge to be derived. The protocol could be the relevant section of a grant application, an institutional research proposal, or a study protocol, including one prepared by a sponsor that is to be followed by the investigators. This information is essential for the IRB to weigh the benefits and risks of the research, and to determine if the informed consent adequately conveys the necessary information to potential study participants.

A research study protocol must be submitted for any research that involves experimental procedures or treatments of human participants.

Section 8: Risks and Benefits of the Research

No research can be considered totally risk free. Even wasting someone's time is a potential risk of poorly designed research. The MDCH IRB must have detailed and accurate information on all potential risks of harm to the research participants and the measures that will be employed to minimize this risk.
There must be some potential benefit from the research. If there is no potential benefit the research cannot be justified, regardless of how low the risk may be. At best there is a direct benefit to the research participant, but there must at least be a potential public benefit. Scientific merit is one of the components of benefit assessment. In order to justify the participation of human participants in research, expected benefits must outweigh the potential risks.

Section 9: Research Records

Investigators are required to maintain the confidentiality of records that can identify individuals, **even indirectly**. Codes can reduce the potential risk of a breach of confidentiality. However, the key to the codes must be kept separately and securely. **If research records are linkable to participants, they must be told about the potential for a breach of confidentiality in the informed consent process and the measures to protect the information.**

Section 10: Costs of the Research

Except in rare circumstances, any costs resulting from the research should not be charged to the research participants or their insurance carriers. Even the latter constitutes an indirect charge, due to the potential for raising premiums.

Section 11: Interviews, Surveys or Group Meetings

Surveys may be included in research involving treatments or procedures, to measure outcomes, or the research may consist only of survey methods. In approaching potential participants to collect information for a survey, **the investigator must clarify that research is in progress**, and that they have no obligation to participate. Survey records that contain personal information, feelings, or opinions may be sensitive, and reveal issues about a person that are embarrassing or incriminating if revealed to others. Some sensitive information could place participants at risk of criminal or civil liability, or be damaging to the person's (or their family's) financial standing, employability or reputation. **Adequate protection of confidential information and a comprehensive informed consent process is required, unless the collected information is recorded in such a way that it cannot be linked to the participants under any circumstance.**

Section 12: Blood Collected from Participants for the Purposes of Research

The estimated volume and frequency of blood to be taken, risks associated with blood removal, and the measures to be taken to minimize those risks **shall** be included in the consent process. There are guidelines for the amount and frequency of blood that can be collected that include considerations of weight, general health, and hematocrit. There are also specific criteria for the frequency and volume of blood that can be collected in a research activity that qualifies for expedited review, under 45 CFR 46.110.

Section 13: This Section Covers Research that is Infrequently Sponsored by the MDCH. Address the issues under each of the following topics in Section 13 of the application, **only if** they apply.

<u>Information on biological specimens (other than blood) taken from participants for research purposes</u>

There are several considerations concerning biological specimens, other than blood, that are used for research. Specimens obtained by invasive means only for research, or surplus specimens that are obtained only for research in the course of obtaining specimens by invasive means for health care, constitute an inherent research risk. A specimen that is obtained only for health care purposes, but is subsequently used for research may involve a research risk related to confidentiality. Certain specimens obtained by non-invasive means or for certain medical reasons (e.g. a placenta taken at delivery) may qualify for expedited review under the provisions of 45 CFR 46.110.

<u>Information on investigational, FDA-exempted drugs, biologics or devices in the research</u>

Drugs, biologics or devices administered to human beings are under the jurisdiction of the US Food and Drug Administration. Applicable regulations are available on the FDA web site (http://www.fda.gov/default.htm).

<u>Information on FDA-approved drugs, biologics or devices in the research</u>

The FDA approves drugs, biologics or devices for human use, for specific indications. A physician may administer an FDA-approved article to a patient for an unapproved health-care indication, without FDA or IRB approval, as long as the physician believes that it will help the patient. On the other hand, the use of an approved article for research requires the involvement of the FDA and an IRB. FDA and IRB involvement are also required in conducting research with drugs, biologics or devices in humans, to compare the efficacy and safety of one approved article with that of another approved article, even if the articles are to be tested within the framework of an approved indication.

Information on ionizing radiation to be administered to research participants

Ionizing radiation includes x-rays, beta rays, gamma rays, neutrons, and other high-speed particles that can produce cumulative biological effects. Human subject research that includes such exposure must provide study participants information on the excess exposure expected from the research, in the context of total possible exposure from all other sources.

Information on any organs, tissues or cells from other humans to be administered to research participants

The primary concern related to transferring, transplanting or administering biological specimens obtained from human beings to other human beings is the possibility of transferring infectious material to the recipient. Testing human-derived biological specimens for all detectable infectious material prior to the transfer to human research participants and informing participants of this potential risk is mandatory.

Information on any genetic material to be transferred to research participants

The transfer of genetic material to human beings is still experimental and subject to strict Federal regulations. Any plans to transfer genetic material must be reviewed by the MDCH IRB. The Office of Recombinant DNA Activities (ORDA) at the National Institutes of Health may decide on a case-by-case basis, whether or not it will also be involved in the approval process. The FDA and ORDA require that gene transfer projects be approved by an Institutional Review Board prior to the submission of the proposal to their agencies.

Section 14: Genetic Analysis Performed on Biological Specimens Obtained from Research Participants

Scientific advances in molecular biology and genetics have raised novel ethical concerns that include:

a) the process to inform the participant and relatives, and/or to provide genetic counseling and screening, when a genetic abnormality or conflicting information on parenthood is discovered,
b) respect for the participant's wish to know, or not know, the result of a genetic study,
c) the process to inform the participant and the proband when the significance of an abnormality is learned at a later date, and this information constitutes a moral obligation to inform the participant about follow-up,
d) the extent of the currently planned genetic analysis, and the extent of potential analysis in the future, when specimens are saved for later studies,
e) the potential for commercialization of the genetic information or of a product resulting from the information.

These concerns do not apply if the participant cannot be linked to the genetic information from the analysis of their biological specimen.

Biological specimens used for genetic analysis in research require the following elements of informed consent when information from the specimen can be linked to the participant:

a) the specific purpose of the genetic analysis,
b) the particular genetic information to be acquired,
c) any known potential consequences of the genetic information to insurability, employability or social esteem of the participant, or to the participant's family,
d) how the genetic information is linkable to the participant and how this link is protected,
e) if the genetic information can be provided to the participant, and if so, an explicit statement that they can chose whether or not to get the information,
f) any provision for genetic counseling,
g) the likelihood of commercialization of the new knowledge and what potential share the participant would have (or not have) in potential financial gains.

If an existing biological specimen had been obtained from a participant without explicit consent for genetic analysis, the MDCH IRB may consider approving genetic analysis on the specimen, only if the investigators acquire the specimen without any identifiers that could link the specimen to the person from whom the sample was obtained.

SECTION 15, RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

Section 15. Research with no direct involvement of human participants but where personal information or biological material, that has been collected, or will be collected, for non-research purposes, or material that will otherwise be discarded, is used for the research.

Existing biological specimens or data are materials already collected prior to the initiation of the research using these materials. 45 CFR 46.101 (b) (4) allows an IRB to exempt "research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the subject." **It is important to note that only the IRB has the power to grant this exemption and it does not mean that such activities are exempt from IRB review.**

If the study material is not publicly available or if the researcher records information in a manner that participants can be identified, **even indirectly**, it is research that requires IRB **approval**. Informed consent is required unless permission to use the material for research was in place at the time the data or specimens were obtained, or the research meets the criteria for waiver of informed consent. If the biological specimens or data are not in existence at the time the research is initiated, the only permissible way the material could be acquired without direct involvement of the participants in the research is for non-research purposes, such as during the course of the delivery of health care. The MDCH IRB expects that the arrangements made by investigators to acquire some of the biological specimens for research be documented as well as the priority of the health care-related use of the specimens. If acquired for non-research purposes, the MDCH IRB may accept an "Institutional Agreement/Permit" as a substitute for a project-specific consent document. If the material is to be acquired for research purposes, the application sections that apply to " **Research with Direct Involvement of Human Participants**" should be used to apply to the MDCH IRB for approval, and a project-specific informed consent should be prepared.

Application Instruction Summary

Sections 1–4 are to be completed for all applications.

Section 1: information needed for tracking and other purposes.
Section 2: determines the application type, and the required sections of the application.
Section 3: provides a concise (limit 300 words) narrative on the research project.
Section 4: provide information on the informed consent process or request waiver.

Sections 5–10, and any relevant Sections of 11-14, must be completed for research that involves direct human subject participation.

Sections 5–10: provides information on research with direct involvement of human participants.
Section 11: provides additional information on interviews, survey instruments, or group meetings.
Section 12: provides information on research blood specimens.
Section 13: provides information on tissue specimens; investigational, FDA-exempted drugs, biologics or devices; FDA-approved, non-investigational drugs, biologics or devices; exposure to ionizing radiation; organs, tissue or cells to be administered; genetic material to be transferred.
Section 14: provides information on the genetic analysis of biological specimens.

Section 15 is for research that does not involve direct human subject participation.

Section 15: provides information on existing human data or biological specimens collected previously or that will be collected, for non-research purposes, or material that will otherwise be discarded.

In finalizing an application for research projects with only direct involvement of human participants, leave blank any of Sections 11–14 that are not relevant, and Section 15. In finalizing an application for research projects with no direct involvement of human participants, leave blank Sections 5–14, and any part of Section 15 that is not relevant.

If the research involves both human subject participation and also a component that does not involve direct human subject participation, complete both the appropriate sections of 5-14 and section 15.

Complete the "Application Completeness Checklist" at the end of the application.